California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE

December 3, 2003
Ramada Inn Burbank Airport
2900 North San Fernando Blvd.
Burbank, CA 91504
(818) 843-5955
9:00 a.m. – 12 noon

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item.

A. Call to Order **9:00 a.m.**

B. Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Specific Examination

C. Report on the Changes to the Pharmacy Technician Program

D. Implementation of SB 490 (Alpert) Chapter 651 – Development of Statewide Protocol for Pharmacists to Dispense Emergency Contraception

E. Consideration of Recommendations for Intern Program Review (CCR, title 16, sections 1727 and 1728)

F. Department of Health Services and Board of Pharmacy Workgroup on Compounding Issues

G. Status Report on the Application Process for Security Printers of Controlled Substance Prescription Documents

H. Tenth Report from the USCF, School of Pharmacy sponsored Study on the Evaluation of Pharmacy Technicians in a Unit-Dose Drug Distribution System

I. Meeting Dates for 2004

Adjournment **12 noon**

Meeting materials will be available on the board's website by November 25, 2003 -- www.pharmacy.ca.gov

Agenda Item B

State of California Department of Consumer Affairs

Memorandum

To: Licensing Committee Date: November 21, 2003

From: Virginia Herold
Assistant Executive Officer

Subject: Implementation on the Board's New Examinations

Staff is working to assure the new examination structure is in place as soon as possible.

The board's staff is negotiating the contracts for the NAPLEX and the California Pharmacist Jurisprudence Examination. Our goal is to be able to issue licenses to pharmacists who have taken (and passed) the new examinations by the end of March 2004. This is the same time as when the board would have been able to license pharmacists had they taken the board's prior exam.

We believe that applicants will be able to take the NAPLEX after January 1, 2004, and have that score be available to California. Applicants must designate California as a score transfer state before they actually take the examination.

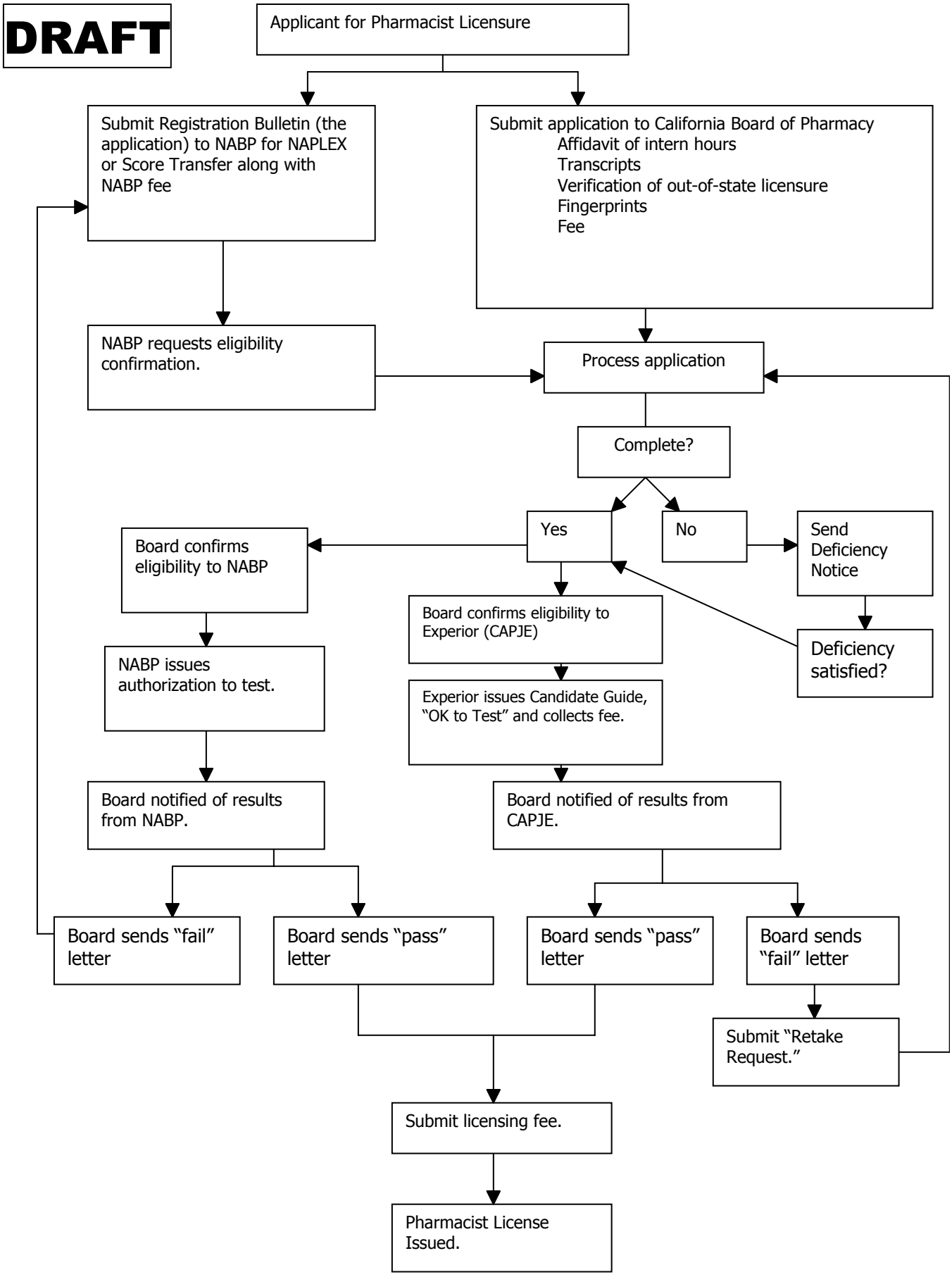
We also believe we will be able to administer the California Pharmacist Jurisprudence Examination via computer terminals in March 2004. We will use the examination vendor under contract with the Department of Consumer Affairs for this portion of the examination instead of the NABP.

The Competency Committee has developed a sufficient item bank of test questions for the new content outline for the examination, a significant task that required monthly meetings since August. The examination items are ready!

Following this page is a flow chart for the new examination process.

We also have added to the board's Web site information about the examination process. We are updating this information periodically. The most recent update is included in this tab section.

DRAFT



Revised 11/21/2003

Becoming Licensed as a Pharmacist in California

Effective January 1, 2004, California will have a new examination program for applicants who seek to become licensed as pharmacists in California. These changes were made by SB 361 (Figueroa, Chapter 361, Statutes of 2003).

The examination process will be comprised of two parts:

1. Passing the North American Pharmacist Licensure Examination (or NAPLEX) which is prepared by the National Association of Boards of Pharmacy. For the score to be valid in California, this exam must be taken and passed after January 1, 2004.
2. Passing the California Pharmacist Jurisprudence Licensure Examination for California. This exam will be developed by the California State Board of Pharmacy and will be available sometime early in 2004; we believe after March 1, 2004. (Note: this exam is different than the Multistate Pharmacist Jurisprudence Examination administered by NABP.)

Both of these examinations will be given via a computer, and will be available for approved applicants to take the examination five days a week, and perhaps six days a week throughout the year.

The new exam structure replaces the board's prior written examination that was given twice a year. The board is **NOT** giving a January 2004 written examination. Instead, passing the two tests listed above will take the place of our former examination. As such, there is no November 2003 deadline to apply to take these examinations (as would have been required if the board continued to give its prior examination).

In order to give these two examinations, contracts must be in place. The California Board of Pharmacy is working to secure these contracts.

The contracts will specify various aspects of how applicants must apply to take the exams, where the exams will be given, deadlines and timelines for applications and other specifics related to the administration of the exams, and release of test scores. At this time, many of these details are not known.

The board believes that these contracts will be finalized in the next few months. The board's goal is to have the contracts in place so the exams can be given no later than March 2004. If so applicants who pass the exam will be eligible for licensure at the beginning of April 2004 – the same time that release of exam scores would have occurred had the board continued to give its prior exam.

After the contracts are in place, candidates will be able to take either of

these examinations throughout the year at multiple locations.

Within several weeks, the board will have an application available online, which can be completed and submitted to the board. This is the first part in the application process where California will review your qualifications to take the pharmacist licensure examination.

The requirements to take the examination will remain the same. Specifically, to take the pharmacist licensure examination for California, you must:

1. Be at least 18 years of age
2. Be a graduate of a domestic school of pharmacy or be a graduate of a foreign school of pharmacy and have passed the Foreign Pharmacy Graduate Equivalency Examination.
3. Have completed at least 150 semester hours of collegiate credit, 90 of which must be from a school of pharmacy
4. Have earned at least a baccalaureate degree in a course of study devoted to pharmacy
5. Have 1,000 hours of approved pharmaceutical experience as a registered intern or one year of experience as a licensed pharmacist in another state.

If you have taken or qualified to take the California pharmacist licensure examination in the past, the board may still have your file. If you have already submitted an application for the January 2004 written examination or postponed taking the June 2003 written examination, the board will soon mail you an information packet detailing the application requirements. The board will apply your $155 application fee to the application fee for the new examination.

If you failed the June 2003 California Licensure Examination, you will need to submit a new application (as stated above, this form will soon be available on the board's Web site).

If you have failed the California licensure exam four times, you are required to complete16 units of remedial education in pharmacy coursework in an ACPE-approved school of pharmacy.

If you wish to take the NAPLEX exam before California has finalized the contract for the new exams, you may apply for licensure as a pharmacist in another state. All other states use the NAPLEX exam. If you do this, you must designate California as a score transfer state before you take the NAPLEX, AND you must take the NAPLEX after January 1, 2004. (Please refer to the Score Transfer Bulletin available on the NABP website for more information.)

The NAPLEX/MPJE Examination Bulletin is available online

(http://www.nabp.net). This manual will assist you in learning about the NAPLEX exam. The California Board of Pharmacy has no involvement with the development of the NAPLEX examination.

Some applicants may also seek to take the PreNAPLEX exam to assist in the test preparation for the NAPLEX. If so, contact the NABP Website for information (http://www.nabp.net).

The board is developing a Candidates' Guide for the California Pharmacist Jurisprudence Examination. This guide will be available from the board's Web site once it is complete.

A copy of the content outline for the California Pharmacist Jurisprudence Examination is already available from http://www.pharmacy.ca.gov/pdfs/exam_outline.pdf.

The board will provide additional information to this Web site as it becomes available. Please be patient. We recognize how important it is to provide application information to you, we are still finalizing details for the process.

Questions and Answers:

The board will provide answers to frequently asked questions at this area of our Web site.

Should you have questions regarding the new examinations, please send them to anne_sodergren@dca.ca.gov. While you will not receive a direct response to your e-mail inquiry, the board will answer those questions with broad applicability. Other, more specific questions will not be answered at this time because many details about the exam program will not be available until the contracting processes are complete.

Questions concerning a specific individual's eligibility or application will **NOT** be answered.

Q: I passed the NAPLEX already and I am licensed in another state, how can I reciprocate my license?
A: The law does not allow for reciprocation. You are required to take and pass both the NAPLEX and California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: When can I take the NAPLEX and California Pharmacist Jurisprudence Exam?
A. The law provides for acceptance of passing scores on the NAPLEX

received after January 1, 2004. The board is currently developing the California Pharmacist Jurisprudence Examination. Please continue to check the Web site for information as to when the California Pharmacist Jurisprudence Examination will be available.

Q: Are the NAPLEX and California Pharmacist Jurisprudence Examination computerized and multiple-choice examinations?
A: Yes

Q: I have already submitted an application for the California January 2004 exam. What do I do?
A: The board will communicate to you in writing with further instructions as soon as procedures are finalized. This may be several months.

Q: When are the revised applications anticipated to be on your website?
A: The applications are currently under legal approval. The board anticipates the applications posted on this Web site in early December.

Q: If the board's applications won't be on the Web site until beginning to mid-November, how can I submit my application by the November 13, 2003 deadline?
A: The November 13, 2003, deadline will not apply to the NAPLEX or California Pharmacist Jurisprudence Examination. Because the board will no longer give its written examination, this deadline is no longer applicable.

Additional questions submitted to the board:

Q: When is the earliest date I can take the NAPLEX?
A: Applicants for California licensure must take and pass the NAPLEX exam after January 1, 2004. There are no exceptions.

Q: I graduate in January, but my transcripts won't be available until February. Can I take the NAPLEX prior to the board receiving my transcripts?
A: No, the board must receive your transcripts with the degree posted before the board will confirm your eligibility to NABP (which qualifies you to the NAPLEX for California).

Q: If I take the MPJE examination offered by the NABP, do I still have the take the California Jurisprudence Examination?
A: Yes. The MPJE examination offered by the NABP is a separate examination required by some states for licensure. It is not a requirement for licensure in California. Rather, applicants must pass the

California Pharmacist Jurisprudence exam in addition to the NAPLEX to become licensed in California. As is stated above the application process for the California exam is not finalized.

Q: I am scheduled to take the NAPLEX examination in January 2004 for another state and would like to transfer my score to California. What are the procedures?
A: Score Transfers are completed by the NAPB. Please visit its Web site www.nabp.net for the specific requirements. Please be advised, however, that the board is still finalizing the contract with the NABP. As such, the NABP may decide not to accept applications for a score transfer to California until after the contract is signed. It is anticipated that the contract will executed by mid-December.

Q: I took the NAPLEX examination in October 2003. Can I transfer this score?
A: No. To become licensed in California, you must take and pass the NAPLEX and the California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: Do I have to wait until March 2004 to take the NAPLEX examination?
A: No. The board will accept a passing score on the NAPLEX examination as long as the examination is taken and passed after January 1, 2004. The NABP will require you to transfer your score according to the NABP's score transfer procedure. (You must request a score transfer prior to taking the NAPLEX.)

Q: Is the California Specific Examination Content Outline posted on your Web site referring to the NAPLEX MPJE examination for California?
A: The content outline posted on the board's Web site is for the California Pharmacist Jurisprudence Examination. There is no NAPLEX MPJE examination required for applicants to become licensed in California. Rather an individual must take and pass the NAPLEX examination and the California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: I heard that the NAPLEX examination is changing after January 1, 2004, and will be more difficult to pass. Is this true?
A: The NAPLEX examination is developed and administered by the NAPB. The board is not aware of any changes being made to this examination.

Q: What do I need to do if I want to take the NAPLEX examination for California?
A: You must submit an examination application to the California Board of Pharmacy and satisfy all of the requirements. You must also submit a "Registration Bulletin" with the NABP to take the NAPLEX.

Q: If I pass the NAPLEX examination but fail the California Pharmcist Jurisprudence examination, do I need to retake both exams or just the California Pharmacist Jurisprudence examination?
A: You will need to retake the California Pharmacist Jurisprudence examination only.

Q: I failed the California Board Examination four times and I am completing the 16 semester units required to reapply in California. At what point can I take the NAPLEX and California Pharmacist Jurisprudence examination?
A: You must complete the 16 semester units prior to reapplying in California.

Q: Your Web site states that the California Pharmacist Jurisprudence exam is different from the MPJE. Does this mean that you don't have to take an MPJE examination in California or is the California Pharmacist Jurisprudence examination taking the place of the MPJE?
A: The California Pharmacist Jurisprudence examination is required. This examination is different than the MPJE administered by the NABP.

Agenda Item C

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: November 20, 2003**

From: **Anne Sodergren**
Staff Services Manager
Board of Pharmacy

Subject: **Changes in the Pharmacy Technician Program**

Effective January 1, 2004, there will be changes to the licensure requirements for applicants seeking registration as pharmacy technicians in California. These changes were made by SB 361 (Figueroa, Chapter 361, Statutes of 2003).

Specifically, changes in Business & Professions Code section 4202 (a) alter the qualifying methods an applicant must satisfy to become registered. After January 1, 2004, to be issued a technician registration, an applicant must satisfy one of the following criteria:

- Obtain an associate's degree in pharmacy technology;
- Complete a course of training specified by the board (this is 240 hours of theoretical and practical training provided by a technician training school or by an employer);
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

Information specific to these changes is available for review on the board's web site as well as resources to obtain information on the associate's degree program and contact information for the PTCB examination. An article will also be included in the January 2004 issue of *The Script.* Staff is working with the department's legal counsel to finalize the new applications. We hope to have the revised applications available within the next few weeks.

This is also an opportunity to streamline our application process and as such the revised applications will not only reflect changes in law, but should reduce the processing time for pharmacy technician applications. We also expect these changes to significantly decrease the number of applications that are received with deficiencies.

Agenda Item D

State of California Department of Consumer Affairs

Memorandum

To: Licensing Committee
Purdue Pharma

Date: November 19, 2003

From: Paul Riches

Subject: Emergency Contraception Protocol

Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the Board of Pharmacy and the Medical Board of California. Prior legislation (Senate Bill 1196, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber.

Staff has drafted the attached draft protocol for the committee's consideration. The draft protocol synthesizes elements from protocols submitted by the Pharmacy Access Partnership and the American College of Obstetricians and Gynecologists. Staff also reviewed protocols from the states of New Mexico and Washington and a sample protocol employed by pharmacists under the existing protocol requirements.

The draft protocol was drafted with an intent to keep the protocol as simple as possible and to comply with the statutory requirements established by Senate Bill 490. The protocol must be approved by both the Board of Pharmacy and the Medical Board of California. The Medical Board of California is awaiting Board of Pharmacy action before taking up the protocol.

Board of Pharmacy
Draft Protocol for Furnishing Emergency Contraception
November 20, 2003

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will assess the need for emergency contraception by determining:

- If patient is requesting EC for emergency use or advance need.
- Date of last menstrual period to help rule out pregnancy.
- If patient is allergic to any medications.

For emergency use:

- If patient had unprotected intercourse within the time limits established for effective use of emergency contraception.

When the pharmacist determines that furnishing emergency contraception is appropriate, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list

must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation*:* Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1 -- Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Brands and Doses Of Oral Contraceptive Tablets Used For Emergency Contraception

Brand	Manufacturer	Tablets per Dose (two doses 12 hour apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Dedicated Emergency Contraceptive Pills				
Plan B	Barr Laboratories	1 white tablet	0	0.75
Preven	Gynétics	2 blue tablets	100	0.05
Oral Contraceptive Pills				
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* Treatment schedule is one dose as soon as possible within three days after unprotected intercourse, and a second dose 12 hours later. For Plan B both doses may be taken together.

** The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

Appendix 2 -- Sample list of Anti-Emetics for Use with Emergency Contraception.

Appendix 3 – Title 16, Section 1707.1 of the California Code of Regulations

§1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, of the Business and Professions Code.
Reference: Sections 4005, 4121 and 4122, of the Business and Professions Code.

Agenda Item E

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: November 21, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Intern Program Review**

One of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website. The Licensing Committee first discussed this issue at its meeting in June. No comments were received in advance of that meeting; however, it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052. Licensing Committee Chair Clarence Hiura invited the deans from the California schools of pharmacy to attend September meeting and requested that they bring recommended changes.

There was discussion that the committee update the experience areas for interns and examples were provided such as detecting and resolving drug related problems and performing disease management; however, no specific written revisions were provided. Much of the discussion focused on the practice site where the intern obtains his/her experience. It was suggested that the "residency model" be used to establish minimum site standards that can be enforced. Another suggestion was for the Competency Committee to perform a comprehensive review of the intern program. It was also suggested that the pharmacist be authorized to supervise more than one intern. The board has policy that supports a ratio of two interns.

Since the last meeting, staff has reviewed the intern program and the recommendations that were put forth at previous meetings. Based on this review, the board should consider placing the intern requirements into statute. Currently, all of the intern requirements are in regulation and it is more appropriate that they be in statute. Therefore, the proposal has been written as statutory language and the program requirements updated accordingly. Also, the following modifications have been included: increasing the ratio to two interns (this is consistent with current board policy), establishing that the intern's pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education, and eliminating the extension provision for the intern permit and the definition of a preceptor.

Requested action: To recommend that the Board of Pharmacy approve the proposed statutory changes for 2004 so that the intern requirements are updated

Board of Pharmacy
Draft Statutory Changes

Amend Section 4005

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; ~~and~~ pertaining to the sale of drugs by or through any mechanical device; and relating to pharmaceutical experience necessary for licensure as a pharmacist.[1]

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.

(d) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Add Section 4026.5

4026.5. "Good standing" means a license issued by the board that is unrestricted by disciplinary action taken pursuant Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.[2]

Amend Section 4030 [3]

4030. ~~"Intern pharmacist" means a person registered with the board pursuant to Section 4200 who shall have completed the educational requirements as determined by the board.~~ Intern pharmacist means a person issued a license pursuant to Section 4208.

Amend Section 4114

4114. ~~An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the supervision of a pharmacist. The pharmacist shall not supervise more than one intern pharmacist at any one time.~~

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board. [4]

(b) A pharmacist shall not supervise more than two intern pharmacists at any one time. [5]

Amend Section 4200

4200. a) The board ~~shall~~ may license as a pharmacist, ~~and issue a certificate to,~~ any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has ~~received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates~~ been certified by the Foreign Pharmacy Graduate Examination Committee[6].

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has ~~had~~ earned 1,500 hours of pharmaceutical experience or the equivalent, in accordance with ~~regulations adopted by the board the~~ Section 4209.[7]

~~(A) "Pharmaceutical experience," constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly~~
~~related to the selling of drugs, compounding physician's prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.~~

~~(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.[8]~~

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits

or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Add Section 4208 [9]

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in Section 4200 subdivision (a), paragraphs (1) – (4).

(c) An intern pharmacist license shall not be issued to a person who failed the examination as required in Section 4200 subdivision (a), paragraph (6) four or more times or to a person who has previously held an intern pharmacist license with the board.

(d) An intern pharmacist shall notify the board within 30 days of any change of address.

(e) An intern pharmacist whose license has been issued pursuant to paragraph (1) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be cancelled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student re-enrolls in a school of pharmacy recognized by the board to fulfill the education requirements of Section 4200 subdivision (a), paragraph (1) – (4).

Add Section 4209 [10]

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before to applying for the pharmacist licensure examination.

(1) This pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education.

(b) An intern pharmacist is required to submit proof of his or her experience on board-approved affidavits, which shall be certified by the pharmacist under whose immediate supervision such experience was obtained.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

This authority was established in Section 4200 (a) (5) and is being moved to consolidate rule-making authority into one section.

[1] This is a commonly used term that needs to be better defined for clarity.
[2] Modify the definition to ensure consistency throughout the law and updating the reference section.
[3] This moves the functions an intern may perform and under what conditions from regulation to statute.
[4] The ratio requirement is becoming a separate subsection and being increased to two consistent with board policy.
[5] Consistent with national standards, the board is requiring full certification. This certification will streamline the board's processing of board required documents.
[6] Intern experience is now defined in Section 4209.
[7] Moved to Section 4209 and specified compliance with the Accreditation Council for Pharmacy Education.
[8] This section moves from regulation to statute the definition of an intern as well as details the licensing requirements.
[9] This section moves the experience requirements an intern must satisfy prior to licensure as a pharmacist from regulation to statute and consolidates information formerly included in Section 4200. This section requires that intern experience must be completed prior to applying and would eliminate a rarely used option for foreign educated applicants to petition the board for 600 hours of intern credit for experienced earned in another country.

choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy school approved by the American Council on Pharmaceutical Education or recognized by the board.
(b) A final examination must be a part of the course of study.
(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

§1726. Preceptor.

(a) A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.
(b) The preceptor shall supervise the intern's activities to provide the experience necessary to make the intern proficient in the provision of pharmaceutical services.
(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1727. Intern Pharmacist.

(a) An intern pharmacist is a person who holds a valid intern card.
(b) An intern card shall be issued for a period of:
(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.
(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.
(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.
(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.
(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:
(1) Persons who have not completed experience requirements.
(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.
(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.
(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1728. Intern Experience--Requirements for Licensure.

(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.

(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.

(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.

(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.

(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:

(1) Receiving and interpreting the prescription;
(2) Patient medication profiles;
(3) Prescription preparation;
(4) Consultation;
(5) Record keeping;
(6) Over the counter products;
(7) Drug information.

(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.

(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.

Authority cited: Sections 4005 and 4114, Business and Professions Code. Reference: Sections 4114 and 4200, Business and Professions Code.

Article 4. Continuing Education

§1732. Definitions.

As used in this article:

(a) An accreditation agency is an organization which evaluates providers of continuing pharmaceutical education, monitors the quality of their educational activities, and audits continuing education coursework.

(b) The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.

(c) The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.

(d) A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.

(e) An hour consists of at least 50 minutes of contact time.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.05. Accreditation Agencies.

(a) The following organizations are approved by the Board as continuing education and accreditation agencies:

Agenda Item F

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: November 21, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Workgroup on Compounding Issues**

At its March 2004 meeting, the Licensing Committee agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy compounding issues, including criteria used by the board to when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

The Licensing Committee agreed to establish a workgroup and to work on the project upon completion of its review of Pharmaceutical Benefit Managers (PBMs) and was added as a committee strategic objective.

Now that the PBM review has been completed, the Licensing Committee should begin the formation of this new workgroup. I suggest that the workgroup have at least two board members as liaison, one from community and one from hospital. Supervising Inspector Dennis Ming will participate and the meetings will be open to the public. A representative from the federal FDA will also be invited to attend. I anticipate that the meetings will be held in Sacramento, with the first meeting sometime next February.

Attached is a letter that the board received from the California Pharmacists Association that identifies some compounding issues that they would like addressed. Also attached is the testimony before a U.S. committee regarding drug compounding by pharmacies.

United States General Accounting Office

GAO

Testimony

Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m.
Thursday, October 23, 2003

PRESCRIPTION DRUGS

State and Federal Oversight of Drug Compounding by Pharmacies

Statement of Janet Heinrich
Director, Health Care—Public Health Issues

GAO-04-195T

October 23, 2003

PRESCRIPTION DRUGS

State and Federal Oversight of Drug Compounding by Pharmacies

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-04-195T, a testimony to the Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

Drug compounding—the process of mixing, combining, or altering ingredients—is an important part of the practice of pharmacy because there is a need for medications tailored to individual patient needs. Several recent compounding cases that resulted in serious illness and deaths have raised concern about oversight to ensure the safety and quality of compounded drugs. These concerns have raised questions about what states—which regulate the practice of pharmacy—and the Food and Drug Administration (FDA) are doing to oversee drug compounding. GAO was asked to examine (1) the actions taken or proposed by states and national pharmacy organizations that may affect state oversight of drug compounding, and (2) federal authority and enforcement power regarding compounded drugs.

This testimony is based on discussions with the National Association of Boards of Pharmacy (NABP) and a GAO review of four states: Missouri, North Carolina, Vermont, and Wyoming. GAO also interviewed and reviewed documents from pharmacist organizations, FDA, and others involved in the practice of pharmacy or drug compounding.

www.gao.gov/cgi-bin/getrpt?GAO-04-195T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

What GAO Found

A number of efforts have been taken or are under way both at the state level and among pharmacy organizations at the national level that may strengthen state oversight of drug compounding. Actions among the four states reviewed included adopting new regulations about compounding and conducting more extensive testing of compounded drugs. For example, the pharmacy board in Missouri is starting a program of random testing of compounded drugs for safety, quality, and potency. At the national level, industry organizations are working on standards for compounded drugs that could be adopted by the states in their laws and regulations, thereby potentially helping to ensure that pharmacies consistently produce safe, high-quality compounded drugs. While these actions may help improve oversight, the ability of states to oversee and ensure the quality and safety of compounded drugs may be affected by state-specific factors such as the resources available for inspections and enforcement.

FDA maintains that drug compounding activities are generally subject to FDA oversight, including its authority to oversee the safety and quality of new drugs. In practice, however, the agency generally relies on states to regulate the limited compounding of drugs as part of the traditional practice of pharmacy. In 1997, the Congress passed a law exempting drug compounders that met certain criteria from key provisions of the Federal Food Drug and Cosmetic Act (FDCA), including the requirements for the approval of new drugs. These exemptions, however, were nullified in 2002 when the United States Supreme Court ruled part of the 1997 law to be an unconstitutional restriction on commercial speech, which resulted in the entire compounding section being declared invalid. Following the court decision in 2002, FDA issued guidance to indicate when it would consider taking enforcement actions regarding drug compounding. For example, it said the agency would defer to states regarding "less significant" violations of the Act, but would consider taking action in situations more analogous to drug manufacturing.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you consider state and federal oversight to ensure the safety and quality of compounded prescription drugs. Drug compounding—the process of mixing, combining, or altering ingredients to create a customized medication for an individual patient—is an important part of the practice of pharmacy. Common examples of compounded drugs include tailor-made medications for patients who are allergic to an ingredient in a manufactured drug. Drug compounding is part of pharmacy education and, like other aspects of pharmacy practice, it is regulated by state pharmacy practice acts, which in turn are enforced by state boards of pharmacy. All 50 states describe drug compounding in their state laws and regulations on pharmacy practice, although specific statutes or regulations vary across states. At the federal level, the Food and Drug Administration (FDA), which oversees the introduction of new drugs into the marketplace under the Federal Food, Drug and Cosmetic Act (FDCA),[1] maintains that compounded drugs are generally subject to the act.

While drug compounding is an important part of ensuring that medications are available to meet individual patient needs, the quality and extent of drug compounding have surfaced as important issues in recent years. For example, several compounding cases in the past several years have resulted in serious illnesses and deaths, raising concern about oversight to ensure the safety and quality of compounded drugs. In addition, concerns have been raised by FDA and others that some pharmacies are going beyond traditional drug compounding for individual patients by, for example, compounding and selling large quantities of drugs without meeting safety and other requirements for new manufactured drugs. Because both states and the federal government have oversight responsibilities, you asked us to address (1) the actions taken or proposed by states and national pharmacy organizations that may affect state oversight of drug compounding, and (2) federal authority and enforcement power regarding compounded drugs.

My testimony today is based in part on discussions with the National Association of Boards of Pharmacy (NABP), as well as a review we conducted of four states: Missouri, North Carolina, Vermont, and Wyoming. We selected these states based on their geographic location and

[1]*See* 21 U.S.C. § 355.

variation in compounding regulations. Two of the states came to our attention as having taken unique steps with regard to oversight of compounded drugs, and the other two had each adopted new regulations on drug compounding. For each of the four states, we reviewed state statutes and regulations, interviewed officials from the state board of pharmacy, and reviewed relevant documents such as pharmacy inspection forms. In addition to examining state-level actions, we examined national industry efforts by interviewing officials from the American Pharmacists Association, the International Academy of Compounding Pharmacists, the American Society of Health-System Pharmacists, the National Association of Chain Drug Stores, and Professional Compounding Centers of America, which provides training to pharmacists and also sells bulk ingredients for drug compounding. We also contacted and obtained information from the United States Pharmacopeia (USP), which is a nonprofit agency that develops standards for pharmaceuticals. Finally, to examine federal authority and enforcement power, we reviewed federal statutes, FDA compliance policy guides, court decisions, and other relevant documents, and interviewed FDA officials and industry experts. We conducted our work from August 2003 to October 2003 in accordance with generally accepted government auditing standards.

In summary, efforts at the state level and among pharmacy organizations at the national level have been taken or are under way to potentially strengthen state oversight of drug compounding. Actions among the four states we reviewed included adopting new statutes and regulations about compounding, such as requirements for facilities and equipment, and conducting more extensive testing of compounded drugs. For example, the pharmacy board in Missouri is starting a program of random testing of compounded drugs for safety, quality, and potency. At the national level, industry organizations are working on standards for compounded drugs that could be adopted by the states in their laws and regulations, thereby helping to ensure that pharmacies consistently produce safe, high-quality compounded drugs. While these actions may help improve oversight, the ability of states to oversee and ensure the quality and safety of compounded drugs may be affected by state-specific factors such as the resources available for inspections and enforcement. For example, in three of the four states we reviewed, pharmacy board officials indicated that resource limitations affected their ability to conduct routine inspections.

FDA maintains that drug compounding activities are generally subject to its oversight, including its authority to oversee the safety and quality of new drugs. In practice, however, the agency generally relies on states to regulate the compounding of drugs as part of the traditional practice of pharmacy. In 1997, the Congress passed a law exempting drug compounders that met certain criteria from key FDCA provisions, including safety and efficacy requirements for the approval of new drugs. However, the entire section of the law dealing with drug compounding was nullified in 2002 after the United States Supreme Court ruled that part of it was an unconstitutional restriction on commercial speech. Following the court decision in 2002, FDA issued guidance to indicate when the agency would consider taking enforcement actions regarding drug compounding. For example, it said the agency would generally defer to the states for "less significant" violations of the FDCA but would consider taking action in situations more analogous to drug manufacturing.

Background

For most people and many pharmacies, filling a prescription is a matter of dispensing a commercially available drug product that has been manufactured in its final ready-to-use form. This has been particularly true in the United States since the rise of pharmaceutical manufacturing companies. In addition to meeting federal safety and efficacy requirements before a new drug is marketed, the drugs manufactured by these companies are routinely tested by FDA after marketing. According to FDA, the testing failure rate for more than 3,000 manufactured drug products sampled and analyzed by FDA since fiscal year 1996 was less than 2 percent. Drug manufacturers are also required to report adverse events associated with their drugs, such as illness and death, to FDA within specified time frames.

Drug compounding, which has always been a part of the traditional practice of pharmacy, involves the mixing, combining, or altering of ingredients to create a customized medication for an individual patient. According to the American Pharmacists Association, some of the most commonly compounded products include lotions, ointments, creams, gels, suppositories, and intravenously administered fluids and medication. Some of these compounded drugs, such as intravenously administered chemotherapy drugs, are sterile products that require special safeguards to prevent injury or death to patients receiving them. For example, sterile compounding requires cleaner facilities than nonsterile compounding, as well as specific training for pharmacy personnel and testing of the compounded drug for sterility.

The extent of drug compounding is unknown, but it appears to be increasing in the United States. While industry representatives, the media, and others have cited estimates for the proportion of prescription drugs that are compounded ranging from 1 percent to 10 percent of all prescriptions, we found no data supporting most estimates.[2] FDA does not routinely collect data on the quantity of prescriptions filled by compounded drugs. Similarly, we found no publicly available data, either from FDA or from industry organizations, on the amount of bulk active ingredients and other chemicals that are used in drug compounding in the United States. However, many state officials, pharmacist association representatives, and other experts we interviewed reported that the number of compounded prescriptions, which had decreased when pharmaceutical manufacturing grew in the 1950s and 1960s, has been increasing over the past decade.

Problems have come to light regarding compounded drugs, some of which resulted in death or serious injury, because the drugs were contaminated or had incorrect amounts of the active ingredient. Unlike drug manufacturers, who are required to report adverse events associated with the drugs they produce, FDA does not require pharmacies to report adverse events associated with compounded drugs. Based on voluntary reporting, media reports, and other sources, FDA has become aware of over 200 adverse events involving 71 compounded products since about 1990. These incidents, including 3 deaths and 13 hospitalizations following injection of a compounded drug that was contaminated with bacteria in 2001, have heightened concern about compounded drugs' safety and quality. In addition, a limited survey conducted by FDA's Division of Prescription Drug Compliance and Surveillance in 2001 found that nearly one-third of the 29 sampled compounded drugs were subpotent—that is, they had less of the active ingredients than indicated.

FDA and others have also expressed concern about the potential for harm to the public health when drugs are manufactured and distributed in commercial amounts without FDA's prior approval. While FDA has stated that traditional drug compounding on a small scale in response to

[2]A 2001 draft report of a study contracted by FDA included an estimate that about 6 percent of all prescriptions were compounded but cautioned that there was considerable uncertainty around this estimate due to limited data. The report acknowledged that definitive statistics on compounding activities were not available. Eastern Research Group Inc., *Profile of the Pharmaceutical Compounding Industry*, draft final report prepared for the Food and Drug Administration, August 27, 2001.

individual prescriptions is beneficial, FDA officials have voiced concern that some establishments with retail pharmacy licenses might be manufacturing new drugs under the guise of drug compounding in order to avoid FDCA requirements.

Actions Taken or Under Way by States and National Organizations to Strengthen State Oversight of Drug Compounding, but Affect Likely to Vary from State to State

We found efforts at the state level and among national pharmacy organizations to potentially strengthen state oversight of drug compounding. Actions among the four states we reviewed included adopting new drug compounding regulations and random testing of compounded drugs. At the national level, industry organizations are working on standards for compounded drugs that could be adopted by states in their laws and regulations. According to experts we interviewed, uniform standards for compounded drugs could help ensure that pharmacists across states consistently produce safe, quality products. While these actions may help improve oversight, the ability of states to oversee and ensure the quality and safety of compounded drugs may be affected by their available resources and their ability to adopt new standards and enforce penalties.

Four States Reviewed Have Taken a Variety of Approaches to Strengthen Oversight

The four states we reviewed have taken a variety of approaches to strengthen state oversight.

- *Missouri.* The pharmacy board in Missouri has taken a different approach from other states: it is in the process of implementing random batch testing of compounded drugs. No other state has random testing, according to an NABP official. Random testing will include both sterile and nonsterile compounded drugs and the board plans on testing compounded drugs for safety, quality, and potency. A Missouri pharmacy board official said testing will include random samples of compounded drugs in stock in pharmacies in anticipation of regular prescriptions, random selection of prescriptions that were just prepared, and testing of compounded drugs obtained by undercover investigators posing as patients. The official added that random testing will help to ensure the safety and quality of compounded drugs and is also intended to serve as a deterrent for anyone who might consider purposely tampering with compounded prescriptions.

- *North Carolina.* North Carolina is the only state in the country that requires mandatory adverse event reporting involving prescription drugs,

including compounded drugs, according to an NAPB official. Regulations in North Carolina require pharmacy managers to report information to the pharmacy board that suggests a probability that prescription drugs caused or contributed to the death of a patient. This reporting system, which does not extend to incidents of illness or injury, allows the board to investigate all prescription-drug-related deaths and determine whether an investigation is warranted.

- *Vermont.* The pharmacy board in Vermont overhauled the state's pharmacy rules in August 2003 to address changes in pharmacy practice, including the increase in Internet and mail-order pharmacies, according to the pharmacy board chairman. For example, the chairman reported that prior to the adoption of the new rules, Vermont had no definition of out-of-state pharmacies and no requirements for these pharmacies to have a Vermont license to do business in the state. The board chairman said that the new rule requiring licensing for out-of-state pharmacies would provide a mechanism to monitor pharmacies that ship prescription drugs, including compounded drugs, into the state. In addition, he added that the board revised the rules for compounding sterile drugs by including specifics on facilities, equipment, and quality assurance measures.

- *Wyoming.* Prior to March 2003, Wyoming did not have state laws or rules that established specific guidelines for drug compounding, aside from a definition of drug compounding, according to a pharmacy board official. The new rules include requirements for facilities, equipment, labeling, and record keeping for compounded drugs, as well as a specific section on compounding sterile drugs. In addition, under the new rules, the official added that pharmacy technicians-in-training are no longer allowed to prepare compounded drugs, including sterile products, which is a more complex procedure requiring special equipment to ensure patient safety.

Efforts of National Organizations May Help States Strengthen Oversight of Drug Compounding

At the national level, industry organizations are working on uniform practices and guidelines for compounded drugs and a committee of national association representatives recently began work on developing a program that would include certification and accreditation for drug compounding that could be used for state oversight. Groups such as the NABP concluded that state oversight of drug compounding would be strengthened if the states had uniform standards and other tools that could be adopted to address the quality and safety of compounded drugs. Several experts that we spoke with said national standards for compounding drugs that could be incorporated into state laws and regulations could help to ensure the quality and safety of compounded drugs. One expert noted that an advantage to incorporating compliance

with national compounding standards into state laws is that it would be easier for states to keep up with updated standards without going through the process of legislative changes.

NABP developed and updated a Model State Pharmacy Act that provides standards for states regarding pharmacy practice. Recently revised in 2003, the model act includes a definition of drug compounding and a section on good drug compounding practices. According to the executive director of NABP, many states have incorporated portions of the model act into their state pharmacy statutes or regulations by including similar definitions of drug compounding and components of NABP's good drug compounding practices. For example, officials in Missouri and Wyoming reported using the model act's good drug compounding practices as a guideline for developing their drug compounding regulations. In addition, USP has established standards and guidelines for compounding nonsterile and sterile drug products, both of which are being updated by expert committees. An official told us that these revisions would be completed early in 2004.

In addition, recognizing that there is no coordinated national program to oversee compounding practices and that states' oversight may vary, NABP recently began working with other national organizations, including the American Pharmacists Association and USP, to create a steering committee to develop a national program to provide a national quality improvement system for compounding pharmacies and the practice of compounding. The committee, which held its second meeting in October 2003, is developing a program that is anticipated to include (1) the accreditation of compounding pharmacies, (2) certification of compounding pharmacists, and (3) requirements for compounded products to meet industry standards for quality medications. To strengthen state oversight of drug compounding, these accreditations, certifications, and product standards, once developed, could be adopted by the states and incorporated into their requirements for compounding pharmacists and pharmacies.

Factors Such as Available Resources May Affect States' Ability to Oversee Compounded Drugs

Although there are several efforts by states and national organizations that may help strengthen state oversight, some states may lack the resources to provide the necessary oversight. State pharmacy board officials in three of the four states reported that resources were limited for inspections, for example:

- The Missouri pharmacy board director reported that pharmacy inspections typically occur every 12 to 18 months; however, an increase in complaints has resulted in less frequent routine pharmacy inspections, because investigating complaints takes priority over routine inspections.

- North Carolina has six inspectors for about 2,000 pharmacies, which the state pharmacy board director said are inspected at least every 18 months. The director added that it is difficult to keep up with this schedule of routine inspections with the available resources while also investigating complaints, which take first priority.

- In Vermont, the pharmacy board chairman reported that, for a period of about 8 years until January 2003, pharmacy inspectors were only able to respond to complaints and not conduct routine inspections because of a shortage of inspectors. Vermont now has four full-time inspectors that cover the state's 120 pharmacies; however, in addition to routine pharmacy inspections, the inspectors are also responsible for inspecting other facilities such as nursing homes and funeral homes. The chairman added that the board would like to have pharmacies inspected annually but it is difficult to keep up with the current schedule of inspections once every 2 years.

Since drug compounding may occur in mail-order and Internet pharmacies, the compounding pharmacy may be located in a state different from the location of the patient or prescribing health professional. Three of the four states we reviewed had a large number of out-of-state pharmacies that were licensed to conduct business in those states, and inspection and enforcement activities may differ for these pharmacies. For example, Wyoming has 274 licensed out-of-state pharmacies, which is nearly twice as many as the number of in-state licensed pharmacies. The four states we reviewed said that they have authority to inspect out-of-state pharmacies licensed in their states but because of limited resources, they generally leave inspections to the state in which the pharmacy is located. Regarding enforcement authority, all four states reported having authority to take disciplinary action against out-of-state pharmacies licensed in their states.

While the pharmacy boards in all four states we reviewed can suspend or revoke pharmacy licenses or issue letters of censure, enforcement mechanisms vary. For example, Missouri and North Carolina are not authorized to charge fines for violations; however, Wyoming can fine a pharmacist up to $2,000 and Vermont can fine a pharmacy or pharmacist $1,000 for each violation. Further, not all state pharmacy boards have the

authority to take enforcement action independently. For example, in Missouri when attempting to deny, revoke, or suspend a license through an expedited procedure, the pharmacy board must first file a complaint with an administrative hearing commission. Only after the commission determines that the grounds for discipline exist may the board take disciplinary action.

Pharmacy board officials reported relatively few complaints and disciplinary actions involving drug compounding. For example, of the 307 complaints received and reviewed by the board of pharmacy against pharmacies and pharmacists in Missouri in fiscal year 2002, only 5 were related to drug compounding.[3]

FDA Asserts Oversight Authority Under FDCA but Generally Relies on States to Regulate Drug Compounding

FDA maintains that drug compounding activities are generally subject to FDA oversight, including the "new drug" requirements and other provisions of the FDCA. In practice, however, the agency generally relies on the states to regulate the traditional practice of pharmacy, including the limited compounding of drugs for the particular needs of individual patients. In recent years, the Congress has attempted to clarify the extent of federal authority and enforcement power regarding drug compounding. In 1997, the Congress passed a law that exempted drug compounders from key portions of the FDCA if they met certain criteria. Their efforts, however, were nullified when the Supreme Court struck down a portion of the law's drug compounding section as an unconstitutional restriction on commercial speech, which resulted in the entire compounding section being declared invalid.[4] In response, FDA issued a compliance policy guide to provide the compounding industry with an explanation of its enforcement policy, which included a list of factors the agency would consider before taking enforcement actions against drug compounders.

[3]The state pharmacy board officials that we spoke with reported that most complaints and disciplinary actions cover dispensing errors related to manufactured drugs, such as incorrectly counting the number of pills for a prescription.

[4]*Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

FDA Asserts Jurisdiction to Regulate Drug Compounding Under FDCA

FDA maintains that FDCA requirements, such as those regarding the safety and efficacy requirements for the approval of new drugs, are generally applicable to pharmacies, including those that compound drugs. The agency recognized in its brief submitted in the 2002 Supreme Court case that applying FDCA's new drug approval requirements to drugs compounded on a small scale is unrealistic—that is, it would not be economically feasible to require drug compounding pharmacies to undergo the testing required for the new drug approval process for drugs compounded to meet the unique needs of individual patients. The agency has stated that its primary concern is where drug compounding is being conducted on a scale tantamount to manufacturing in an effort to circumvent FDCA's new drug approval requirements. FDA officials reported that the agency has generally left regulation of traditional pharmacy practice to the states, while enforcing the act primarily when pharmacies engage in drug compounding activities that FDA determines to be more analogous to drug manufacturing.

FDA Modernization Act Exempted Drug Compounders from Some FDCA Requirements but Was Declared Invalid

Federal regulatory authority over drug compounding attracted congressional interest in the 1990s, as some in the Congress believed that "clarification is necessary to address current concerns and uncertainty about the Food and Drug Administration's regulatory authority over pharmacy compounding."[5] The Congress addressed this and other issues when it passed the FDA Modernization Act of 1997 (FDAMA), which included a section exempting drugs compounded on a customized basis for an individual patient from key portions of FDCA that were otherwise applicable to manufacturers.[6] According to the congressional conferees, its purpose was to ensure continued availability of compounded drug products while limiting the scope of compounding so as "to prevent manufacturing under the guise of compounding."[7]

In order to be entitled to the exemption, drug compounders had to meet several requirements, including one that prohibited them from advertising or promoting "the compounding of any particular drug, class of drug, or

[5]S. Rep. No. 105-43, at 67 (1997).

[6]These portions covered "adequate directions for use" labeling, manufacturing, and new drug approval requirements. *See* former 21 U.S.C. § 353a (a). Pub. L. No. 105-115, 111 Stat. 2296, former section 503A.

[7]H.R. Conf. Rep. No. 105-399, at 94 (1997).

type of drug."[8] This prohibition was challenged in court by a number of compounding pharmacies and eventually resulted in a 2002 Supreme Court decision holding that it was unconstitutional. As a result, the entire drug compounding section was declared invalid.[9] However, the Court did not address the extent of FDA's authority to regulate drug compounding.

Current FDA Enforcement Focuses on Drug Compounding Outside of the Traditional Practice of Pharmacy

FDA issued a compliance policy guide in May 2002, following the Supreme Court decision, to offer guidance about when it would consider exercising its enforcement authority regarding pharmacy compounding.[10] In the guide, FDA stated that the traditional practice of drug compounding by pharmacies is not the subject of the guidance. The guide further stated that FDA will generally defer to state authorities in dealing with "less significant" violations of FDCA, and expects to work cooperatively with the states in coordinating investigations, referrals, and follow-up actions. However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of FDCA, the guide stated that FDA has determined that it should seriously consider enforcement action and listed factors, such as compounding drug products that are commercially available or using "commercial scale manufacturing or testing equipment," that will be considered in deciding whether to take action.[11]

[8]*See* former 21 U.S.C. § 353a (c).

[9]Both the district and appellate courts held that the prohibition was unconstitutional. However, the district court held that the prohibition was "severable" and that the rest of the pharmacy compounding section remained good law. While the appellate court agreed with the district court on the constitutional question, it disagreed on the severability issue and invalidated the entire section. The Supreme Court agreed with both courts on the constitutional issue, but because the severability decision was not challenged, the Court did not rule on it, and left it in place. *See Thompson v. Western States Medical Center*, 69 F. Supp. 2d 1288 (D. Nev. 1999), aff'd in part and rev'd in part, 238 F. 3d 1090 (9th Cir. 2001), aff'd, 535 U.S. 357.

[10]This guide was similar to an earlier compliance policy guide published by FDA in 1992. After the drug compounding section of FDAMA was declared invalid, FDA determined that it needed to issue new guidance to the compounding industry on what factors the agency would consider in exercising its enforcement discretion regarding drug compounding.

[11]"Compliance Policy Guide: Compliance Policy Guidance for FDA Staff and Industry", Chapter 4, Sub Chapter 460, May 2002.

Some representatives of pharmacist associations and others have expressed concern that FDA's compliance policy guide has created confusion regarding when FDA enforcement authority will be used. For example, some pharmacy associations assert that FDA's guidance lacks a clear description of the circumstances under which the agency will take action against pharmacies. In particular, they pointed to terms in the guide, such as "very limited quantities" and "commercial scale manufacturing or testing equipment" that are not clearly defined, and noted that FDA reserved the right to consider other factors in addition to those in the guide without giving further clarification. FDA officials told us that the guide allows the agency to have the flexibility to respond to a wide variety of situations where the public health and safety are issues, and that they plan to revisit the guide after reviewing the comments the agency received, but did not have a time frame for issuing revised guidance.

In several reported court cases involving FDA's regulation of drug compounders, the courts have generally sided with FDA. Two cases we identified involved drug compounders engaged in practices that were determined to be more analogous to drug manufacturing. In a district court case decided this year, the court upheld FDA's authority to inspect a pharmacy specializing in compounding, noting that it believed that FDA's revised compliance policy guide was a reasonable interpretation of the statutory scheme established by FDCA.[12]

Concluding Observations

While drug compounding is important and useful for patient care, problems that have occurred raise legitimate concerns about the quality and safety of compounded drugs and the oversight of pharmacies that compound them. However, the extent of problems related to compounding is unknown. FDA maintains that drug compounding activities are generally subject to FDA oversight under its authority to oversee the safety and quality of new drugs, but the agency generally relies on states to provide the necessary oversight. At the state level, our review provides some indication that at least some states are taking steps to strengthen state oversight, and national pharmacy organizations are developing standards that might help strengthen oversight if the states adopted and enforced them. However, the effectiveness of these measures is unknown, and

[12] *In the Matter of Establishment Inspection of Wedgewood Village Pharmacy, Inc.*, 270 F. Supp. 525, 549 (D. N.J. 2003).

factors such as the availability of resources may also affect the extent of state oversight.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

Contact and Acknowledgments

For further information, please contact Janet Heinrich at (202) 512-7119. Individuals making key contributions to this testimony included Matt Byer, Lisa A. Lusk, and Kim Yamane.

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Of Counsel: ALLEN D. EMMEL*

RECEIVED BY CALIF. BOARD OF PHARMACY
2003 SEP 10 PM 1:28

September 3, 2003

Enforcement Committee
c/o Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R. Street, Suite 4070
Sacramento CA 95814

Re: Compounding Issues: Labels and Central Fill

Dear Enforcement Committee:

On behalf of several clients and the Compounding Pharmacists Section of the California Pharmacists Association, thank you for putting these issues on the agenda for the next Enforcement Committee Meeting.

1. Labels on Compounded Products.

An issue that has been brought to the attention of several compounding pharmacists involves the appropriate content of labels of compounded products. There is widespread agreement with the Board that current label requirements reflect information that is needed by consumers when they receive compounded products. The problem arises when the compounded product is provided in multiple units of a dosage form – i.e. suppositories, single dose vials, etc. – for which individual product labels are either not feasible, cost prohibitive or even a hindrance to treatment. For instance, many creams are dispensed in application syringes that contain multiple doses of the product. Graduations on the syringes are used to measure the individual dose. Because of their size, placing a label on each syringe would obstruct these graduations, making accurate dosing difficult or impossible.

The question raised is: What, if any, information does the Board feel should be included on individual units of compounded products that are dispensed to patients?

In the opinion of the pharmacists we surveyed, this should be a matter for the individual discretion of the compounding pharmacist. In many cases, individual doses should contain some sort of label to indicate the active ingredients. The form of this label will vary depending on the dispensing unit and available space. In other cases, a label on individual doses will result in little or no benefit and will cause more problems than it solves. In the case of compounded tablets and capsules, identification of any kind on individual doses simply isn't practical.

In any case, the patient should be made aware of the situation and advised to always keep the doses in the box, bag or container in which it was dispensed and which is labeled with the information that may be needed by a family member or emergency personnel in the event of a problem.

To clarify existing law and resolve any conflicts that may arise, we ask that the Board of Pharmacy weigh in on this issue. We welcome the opportunity to participate in a dialog to reach a reasonable and agreeable guideline for labels on compounded products.

2. Compounding in Central Fill Pharmacies

Many pharmacists and pharmacies are specializing in compounded products. The value of these products is broadly recognized. The Board's recent activities with regard to compounding of sterile injectable products has provided needed focus on the systems and facilities needed for the safe compounding of sterile injectables.

For a large number of compounded products, similar, if less stringent, systems and facilities are needed for the preparation of products to assure consistency in preparation and potency. Pharmacies that specialize in this practice have invested in those systems and facilities and, as evidenced by the growth in this area of practice, the products they compound are accepted as effective and safe.

We believe consumers should have improved access to compounded products. A safe and cost-effective way to accomplish this is to allow compounding pharmacies to act as central fill pharmacies for compounded products in the same way as is allowed for other prescriptions under CCR 1707.4. The Board has authorized similar activity for parenteral products for many years (cf B&P sec. 4123). We believe allowing central filling of compounded products under the provisions of 1707.4 will improve access for consumers, reduce costs and result in the provision of more consistent, safer and more effective compounded products.

We ask the Board to move forward on this proposal and are willing to work with the Board to resolve any problems that stand in the way of this application of section 1707.4.

I look forward to discussing these proposals further at the upcoming Enforcement Committee meeting.

Sincerely,

John Cronin

John Cronin, Pharm.D., J.D.

Agenda Item G

Memorandum

Date: November 24, 2003

To: Licensing Committee
California State Board of Pharmacy

From: Sue Durst, Enforcement Analyst

Re: Status of the Security Printer Approval Process

Senate Bill 151 requires the Board of Pharmacy, in coordination with the Department of Justice (DOJ), to approve security printers prior to the production of secure prescription forms for controlled substances. Staff has been busy developing draft procedures for the review and approval of security printers, coordinating the approval process with the DOJ, and developing the necessary forms, letters, worksheets, checklists and instructions that will be used.

An initial kickoff meeting with board staff was held on November 4, 2003 to review a draft application and discuss the board's vision for the approval process. Several changes to the application and process were noted. We are currently incorporating these changes and defining in greater detail the criteria for approval/denial.

Later that morning, board staff met with representatives from Bureau of Narcotics Enforcement and Department of Justice to review the draft security printer application and discuss the approval process. The DOJ agreed to the basic process and draft application with a few noted changes. Staff from the Bureau of Narcotics Enforcement, CURES Program, will be the board's partner in the application approval process. The BNE intends to search various internal criminal databases as part of their review and approval process. DOJ is checking on the legality of sharing criminal records and fingerprints across agencies.

Board staff plan to have a final draft of the application packet ready for review by Legal the end of this week. We anticipate the application packet to be available on the board's website mid December.

Agenda Item H

UCSF
University of California
San Francisco

LA/OC Area Clerkship Program
Department of
Pharmacy Services
Long Beach Memorial
Medical Center
2801 Atlantic Avenue
P.O. Box 1428
Long Beach, CA 90801-1428
tel: 562/933-0289
fax: 562/933-2348

October 31, 2003

Patricia F. Harris
Executive Director
California State Board of Pharmacy
400 "R" Street, Suite 4070
Sacramento, CA 95814-6200

Re: Technician Study – Tenth Report

Dear Ms. Harris:

This is our tenth report of the experimental program to evaluate pharmacy technicians in a unit-dose drug distribution system; sponsored by the UCSF School of Pharmacy, in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study began in June 1998 and is continuing through December 2003.

Additions and deletions of certified pharmacy technicians since my last report are listed on the attached documents for CSMC. The quality assurance audits were conducted at both institutions, and the audit data is also attached.

It is my understanding that the waiver granted for this study will expire at the end of this year, and both institutions are aware of this.

Respectfully submitted,

Peter J. Ambrose, Pharm.D.
Professor of Clinical Pharmacy

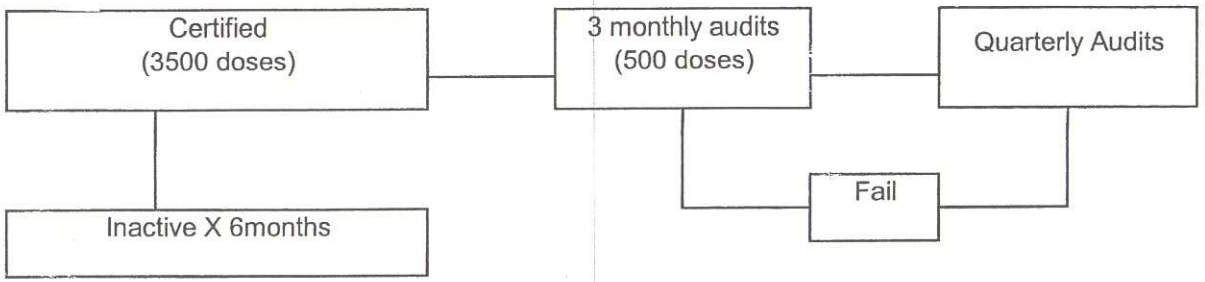
Enclosures:
Eligible Technician Checkers – Cedars Sinai Medical Center
Audits – Cedars Sinai Medical Center
Audits – Long Beach Memorial Medical Center

c: Frank Saya, Pharm.D.
Dale Adams, Pharm.D.
Rita Shane, Pharm.D.

Long Beach Memorial Medical Center
June 2003

No.	Last Name	First Name	Reg. #	CERTIFICATION Name Submitted in	MONTHLY AUDITS Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99
1					I	I	I	C	I	C
3					C	C	I	I	I	I
11									C	A
12									C	A
13										C
16										
17										
18										
19										
20										
21										
22										
23										
				Ave. Accuracy Rate	99.9%	99.9%	99.8%	99.8%	99.9%	99.9%

C =Certifying
A =passed Audit
F =Failed audit
I =Inactive
rC = Recertification



MKI/EXCEL
TCT

Long Beach Memorial Medical Center
June 2003

Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00
A	A	A	I	I	I	I	I	I	I	rC(379)	I	I	I	rC(1174)
A	A	A	I	I	I	I	I	I	I	I	rC(635)	I	I	rC(258)
A	A	A	A		A		A				A			
A	A	A	A	A			A				A			
A	A	A	A	A			I	I	I		A			
			C	A	I	I	I	I	I	I	I	I	I	rC(865)
									C	I	I	I	I	rC(612)
										C	A	I		
99.9%	99.9%	99.9%	99.9%	99.9%	100.0%		99.9%		99.9%	99.8%	99.9%		99.8%	99.8%

MKI/EXCEL
TCT

Long Beach Memorial Medical Center
June 2003

Quarterly Audits

Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02	Feb-02	Mar-02
rC(982)	I	I	I	I	I	rC(1102)								
I	I	I	rC(1078)	I	rC(2043)	I	A(550)	A(511)	A(625)			A(522)		A(555)
I	I	rC(992)	rC(513)	I	I	rC(1824)	A(586)	A(589)	A(727)			A(1029)		A(572)
I	I	I	I	I	I	rC(1008)	rC(1388)			rC(1150)	A(1027)			rC(1243)
						C(3617)	A(1080)	A(585)	A(1458)				rC(1464)	
							C(3008)							
							C(2822)							
99.8%	99.8%	99.8%	99.8%		99.9%	99.9%	99.9%	99.9%	99.9%	100.0%	100.0%	99.9%	99.9%	99.9%

MKI/EXCEL
TCT

Long Beach Memorial Medical Center
June 2003

Apr-02	May-02	Jun-02	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03
		A(525)		A(659)			A(554)			A(542)
rC(846)										
99.9%		99.9%		99.9%			99.9%			99.9%

Recertified (3500)
YES = 3637
Certified + 3 audits + Qtrly

MKI/EXCEL
TCT

MCH Tech check Tech Audits

Technician	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	Jul-03
		A(548)			A(644)	A(530)
	C(1620)	C(509)	C552)	C524)	A(594)	A(525)
		A(545)			A(644)	A(501)
		A(692)			A(592)	A(515)
		A(586)			A(6008)	A9563)
		A(606)			A(561)	A(983)
		LOA			A(573)	A(518)

A=monthly audit
C=certification audit
I=inactive
LOA=medical leave

Table 3

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Reg. #	Name Submitted In	MONTHLY / QUARTERLY AUDITS								MONTHLY / QUARTERLY AUDITS								
					Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00
1					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
2					Newly certified	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
3																Newly certified	Passed	Passed	Passed	Passed	Passed	Passed
4																						
5					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed										
6					Newly certified	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
7					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
8								Newly certified	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
9																						
10					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
11					Newly certified	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
12					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
13					Passed	Passed	Passed	Passed	Passed	Passed	Passed (2nd try)	Passed (2nd try)	Passed	Passed			Passed			Passed		
14					Newly certified	Passed	Passed	Passed	Passed	Passed	Passed (2nd try)	Passed (2nd try)	Passed	Passed			Passed			Passed		
15					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
16									Newly certified	Passed	Passed	Passed	Passed	Passed	Passed		Passed			Passed		
17					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
18					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed								
19					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Maternity Leave				Passed			Passed		
20					Passed	Passed	Passed	Passed	Passed	Passed	Passed (2nd try)	Passed	Passed	Passed			Passed			Passed		
21					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed (2nd try)	Passed	Passed			Passed			Passed		
22					Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
23					Passed	Passed (2nd try)	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed								
24					Passed	Passed	Passed	Passed	Passed	Passed												
25					Passed (2nd try)	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed			Passed			Passed		
26					Passed (2nd try)	Passed	Passed	Passed	Passed	Passed	Passed	Passed (2nd try)	Passed	Passed			Passed			Passed		
	AVERAGE ACCURACY				99.91%	99.89%	99.86%	99.89%	99.96%	99.94%	99.92%	99.90%	99.85%	99.86%			99.97%			99.98%		

Table 3

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Oct-00	Nov-00	Dec-00	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02	Feb-02	Mar-02	Apr-02	May-02	Jun-02	Jul-02
1			Passed			Passed			Passed			Passed			Passed									
2			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
																			Newly Certified	Passed	Passed	Passed	Passed	Passed
3			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
4																			Newly Certified	Passed	Passed	Passed	Passed	Passed
5																								
6			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
7			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
8			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
9																			Newly Certified	Passed	Passed	Passed	Passed	Passed
10			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
11			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
12			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
13			Passed			Passed			Passed															
14																			Newly Certified	Passed	Passed	Passed	Passed	Passed
15			Passed			Passed			Passed			Passed			Passed									
16			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
17																								
18																								
19			Passed			Passed			Passed			Passed			Passed			Passed			Passed			
20			Passed			Passed			Passed			Passed			Passed									
21			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
22			Passed			Passed			Passed			Passed			Passed									
23																								
24																								
25			Passed			Passed			Passed			Passed			Passed									
26			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
		AVERAGE	99.92%			99.94%			99.97%			99.99%			100%			99.95%			99.95%			99.91%

Table 3

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	Jun-03	Jul-03
1													
2					Passed			Passed			Passed		
			Passed		Passed			Passed			Passed		
3					Passed			Passed			Passed		
4			Passed		Passed			Passed					
5													
6					Passed			Passed			Passed		
7					Passed			Passed			Passed		
8					Passed			Passed			Passed		
9			Passed		Passed			Passed			Passed		
10					Passed								
11					Passed			Passed			Passed		
12					Passed			Passed			Passed		
13													
14			Passed		Passed			Passed			Passed		
15													
16					Passed			Passed			Passed		
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21					Passed			Passed			Passed		
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24													
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26					Passed			Passed			Passed		
		AVERAG			99.88%			99.97%			99.98%		